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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,703	09/26/2001	Subba Reddy Palli	A01020B	8135

7590 06/13/2005
RheoGene Holding Inc
2650 Eisenhower Avenue
Norristown, PA 19403

EXAMINER

MURPHY, JOSEPH F

ART UNIT PAPER NUMBER

1646

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,703

Applicant(s)

PALLI ET AL.

Examiner

Joseph F. Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 13, 14 and 16-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11 and 12 is/are rejected.
- 7) ☒ Claim(s) 7 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

Claims 1-36 are pending. Claims 1-7, 11-12, 15 are under consideration. Claims 8-10, 13-14, 16-36 stand withdrawn from consideration pursuant to 37 CFR 1.142(b).

Response to Amendment

The rejection of claims 1, 3 under 35 U.S.C. 102(b) as being anticipated by Leonhardt et al. (1998) have been obviated by Applicant's amendment and are thus withdrawn.

The rejection of claims 1, 3-5, 11 under 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. (1998) in view of U.S. 59191667 (Gage et al.) have been obviated by Applicant's amendment and are thus withdrawn.

New issues are set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Licitra et al. (1996).

The instant claims are drawn to a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP, wherein the LBDs are different. The claims are further drawn to gene expression modulation systems comprising a

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third gene expression cassette comprising a response element and a gene whose expression is to be modulated. The claims are anticipated by the Licitra reference that teaches the yeast three-hybrid system. The three hybrid system comprises a first gene expression cassette comprising the DNA-binding domain and a ligand binding domain; a second gene expression cassette comprising a different ligand binding domain and a transactivation domain, and a third gene expression cassette comprising a response element and a reporter gene (see page 12819, Figure 2). Since the Licitra reference teaches all the elements of the claims, the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-6, 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licitra et al. (1996) in view of U.S. 59191667 (Gage et al.).

The instant claims are drawn to a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP, wherein the LBDs are different, wherein the LBDs are from RXR and ecdysone receptor. The claims are further drawn to gene expression modulation systems comprising a third gene expression cassette comprising a response element and a gene whose expression is to be modulated. The Licitra reference teaches the yeast three-hybrid system. The three hybrid system comprises a first gene expression cassette comprising the DNA-binding domain and a ligand binding domain; a second gene expression cassette comprising a different ligand binding domain and a transactivation domain, and a third gene expression cassette comprising a response element and a reporter gene (see page 12819, Figure 2). The Licitra reference differs from the instant claims in not teaching LBDs from RXR or ecdysone receptor. However, , the '667 patent discloses a transgenic animal contains one or more expression constructs containing nucleic acid encoding an ecdysone receptor, exogenous RXR, and an heterologous gene under the transcription control of an ecdysone response element. Therefore, it would have been obvious to one of skill in the art at the time the invention was made to make a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD, wherein the LBD is an ecdysone receptor (EcR) LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP; and a reporter gene vector comprising a response element to the DBD of the first vector, wherein the gene expression system comprises an ecdysone receptor and an

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exogenous RXR. The motivation is provided in the '667 patent which discloses that transgenic mice containing an ecdysone response element and expressing ecdysone receptor and RXR, muristerone treatment can activate gene expression. Thus, with tissue specific expression of ecdysone receptor and RXR and timely hormone treatment, inducible gene expression can be achieved with spatial, dosage, and temporal specificity.

Conclusion

Claims 1-6, 11-12 are rejected.

Claims 7, 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Advisory Information

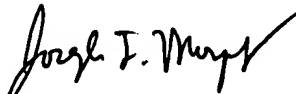
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (571) 272-0829.

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The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Primary Examiner
Art Unit 1646
June 2, 2005



JOSEPH MURPHY
PATENT EXAMINER